K133905

APR 15 2014

Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

Submitter Information

Esaote S.p.A.
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Date: March 17, 2014

807.92(a)(2)

Devices

Common Name: Ultrasound Imaging System

Trade Name: 6200 Ultrasound System
6250 Ultrasound System

Classification Name(s): Ultrasound Pulse Doppler Imaging System 892.1550
Ultrasound Pulse Echo Imaging System 892.1560
Transducer, Ultrasonic, Diagnostic 892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

Predicate Device(s)

Device	Owner	510(k)
6200	Esaote	K100931
6250	Esaote	K103152
Virtual Navigator Software	Esaote	K081386
GE Logiq E9 with Volume Navigation	GE	K123564

807.92(a)(4)

Device Description

Both 6200 and 6250 models are mainframe ultrasound systems used to perform diagnostic general ultrasound studies. The primary modes of operation are for both systems: B-Mode, M-Mode, XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). Both 6200 and 6250 are equipped with an LCD color display where acquired images and advanced image features are shown.

The Virtual Navigator is a software option designed to support a radiological clinical ultrasound examination (first modality) and follow a percutaneous procedure providing additional image information from a 2nd imaging modality (CT, MR or US). The user is helped in assessing the patient anatomy by displaying the image generated by the 2nd modality.

6200 models including Virtual Navigator software option have been cleared by k100931; 6250 models including Virtual Navigator software option have been cleared by k103152.
Virtual Navigator has also been cleared for use with 6100 and 6150 models by k081386.

The purpose of this submission is to introduce an upgrade to both Esaote 6200 and 6250 models to add additional software capabilities. 6200 and 6250 Upgrades, defined herein, combine the cleared features of both 6200 and 6250 models with other new software capabilities related to the Virtual Navigator software option and listed below:

- Navigation Software - new user interface
- Tracking System – new Ascension tracking module managing also needle and motion sensors
- Second Modality Data Acquisition - multi dataset management (MRI, PET, CT, US via Dicom – US including acquisition and navigation)
- New Indications: Gynecological, Obstetrics, Pediatric, Small Organs, Transcranial
- Registration Techniques – added one point registration
- Target Definition – introduced intelligent positioning
- Planning - updated needle table
- 3D Panoramic

The 6200 and 6250 Upgrades are manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use

Esaote's Model 6200 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6200 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 6250 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6250 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The Virtual Navigator software option for Esaote models 6200 and 6250 is intended to support a radiological clinical ultrasound examination (first modality) and follow percutaneous procedures or surgical operations providing additional image information from a second imaging modality (CT, MR, US and PET). The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Gynecological, Musculo-skeletal, Obstetrics, Pediatric, Urologic, Small Organs, Peripheral Vascular and Transcranial for radiological examinations only.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

807.92(a)(6)

Technological Characteristics

The 6200 and 6250 Upgrades employ the same fundamental technological characteristics as their predicated devices. The 6200 Upgrade model is substantially equivalent to Esaote 6200 model cleared by FDA via K100931. The 6250 Upgrade model is substantially equivalent to Esaote 6250 model cleared by FDA via K103152. The Virtual Navigator software is substantially equivalent to prior clearances in K100931, K103152 and K081386. Additional features of the Virtual Navigator are substantially equivalent to the GE Volume Navigation as cleared on the GE Logiq E9 via K123564.

- Clinical uses for which both 6200 and 6250 are designed are not changed by the 6200 and 6250 Upgrades, to be cleared with this submission.
- Clinical uses for which both 6200 and 6250 Upgrades are equivalent to those of Esaote 6200 model, cleared via k100931, and of Esaote 6250 model, cleared via k103152.
- Clinical uses for which Virtual Navigator is designed are the same of the 6200 and 6250 systems.
- Clinical uses for which Virtual Navigator Upgrades are equivalent to those of General Electric Volume Navigation on the Logiq E9, cleared via k123564.
- Esaote 6200, 6250 and General Electric (GE) Logiq E9 ultrasound systems are equipped with a software option designed to support a radiological clinical ultrasound examination (first modality) and follow a percutaneous procedure providing additional image information from a second imaging modality (CT, MR or US). Virtual Navigator was originally FDA cleared via k081386 with Esaote 6100 and 6150 models, and was subsequently cleared for use with the Esaote 6200 and 6250 models via k100931 and k103152, respectively. The GE Volume Navigation has been cleared via k123564.
- Esaote 6200, 6250 and General Electric Logiq E9 ultrasound systems are able to acquire volumetric dataset using motorized probe. Esaote 3D/4D mode with motorized probes has been FDA cleared via k100931 for 6200 model and via k103152 for 6250 model, General Electric 3D/4D mode has been FDA cleared via 082185.
- Esaote 6200, 6250 and General Electric Logiq E9 are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 6200, 6250 and General Electric Logiq E9 provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

807.92(b)(1)

Summary of Non-Clinical Tests

The devices have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 6060 1-2-37
- NEMA UD-3 - Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 - Acoustic Output Measurement Standard for Diagnostic Ultrasound
- ISO 14971
- ISO 62304

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The 6200 and 6250 Upgrades are substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 15, 2014

ESAOTE S.P.A.
C/O ALLISON SCOTT
NAVIGANT CONSULTING, INC.
9001 WESLEYAN ROAD, SUITE 200
INDIANAPOLIS, IN 46268

Re: K133905
Trade/Device Name: 6200 Ultrasound System, 6250 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: March 17, 2014
Received: March 18, 2014

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the 6200 and 6250 Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

CA123	CA421	CA430	CA431
C5-2 R13	CA541	CA621	CA631
SC3123	LA332	LA435	LA522
LA523	LA532	LA533	LA923
SL3116	PA023	PA122	PA230
PA240	BC431	BC441	BC433
BE1123	EC123	EC1123	TEE022
TEE132	IOE323	IOT332	IOT342
LP323	TRT33	2CW	5CW
HFCW			

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133905

Device Name
6200 and 6250 Ultrasound Systems

Indications for Use *(Describe)*
Esaote's Model 6200 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6200 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote's Model 6250 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6250 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The Virtual Navigator software option for Esaote models 6200 and 6250 is intended to support a radiological clinical ultrasound examination (first modality) and follow percutaneous procedures or surgical operations providing additional image information from a second imaging modality (CT, MR, US, and PET). The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Gynecological, Musculo-skeletal, Obstetrics, Pediatric, Urologic, Small Organs, Peripheral Vascular and Transcranial for radiological examinations only.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

6200

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Oth
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	I
Abdominal	P	P	P	P	P	P	P		P	I
Intraoperative (Abdominal)	P	P	P	P	P	P	P		P	I
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	I
Small Organs [1]	P	P	P	P	P	P	P		P	I
Neonatal Cephalic	P	P	P	P	P	P	P		P	I
Adult Cephalic	P	P	P	P	P	P	P		P	I
Cardiac [2]	P	P	P	P	P	P	P	P	P (8)	I
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	I
Transesophageal (Non Cardiac)										
Transrectal	P	P	P	P	P	P	P		P	I
Transvaginal	P	P	P	P	P	P	P		P	I
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	I
Laparoscopic	P	P	P	P	P	P	P		P	I
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P		P	I
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P		P	I
Other (Urological)	P	P	P	P	P	P	P		P	I

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

6250

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P:
Abdominal	P	P	P	P	P	P	P		P	P:
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P:
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P:
Small Organs [1]	P	P	P	P	P	P	P		P	P:
Neonatal Cephalic	P	P	P	P	P	P	P		P	P:
Adult Cephalic	P	P	P	P	P	P	P		P	P:
Cardiac [2]	P	P	P	P	P	P	P	P	P [8]	P:
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P:
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P:
Transvaginal	P	P	P		P	P	P		P	P:
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P:
Laparoscopic	P	P	P		P	P	P		P	P:
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P		P	P:
Other (Urological)	P	P	P	P	P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

CA123 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P		P	P:
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

CA421 (6250 system only)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k103152

Prescription Use Only Per 21 CFR 801 Part D

Concurrence of Center for Devices and Radiological Health (CDRH)

CA430 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (s
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5,
Abdominal	P	P	P		P	P	P		P	P: 5,
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P: 5,
Small Organs [1]	P	P	P		P	P	P		P	P: 5,
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P: 5,
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P: 5,
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P: 5,
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P: 5,
Other (Urological)	P	P	P		P	P	P		P	P: 5,

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

CA431 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

C5-2 R13 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

CA541 (6200 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931

Prescription Use Only Per 21 CFR 801 Part D

Concurrence of Center for Devices and Radiological Health (CDRH)

CA541 (6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E:
Abdominal	E	E	E		E	E	E		E	E:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E:
Small Organs [1]	E	E	E		E	E	E		E	E:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	E	E	E		E	E	E		E	E:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E:
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E:
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:
Other (Urological)	E	E	E		E	E	E		E	E:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via Appendix E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

CA621 (6250 systems only)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k103152

Prescription Use Only Per 21 CFR 801 Part D

Concurrence of Center for Devices and Radiological Health (CDRH)

CA631 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SC3123 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E:
Abdominal	E	E	E		E	E	E		E	E:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E:
Small Organs [1]	E	E	E		E	E	E		E	E:
Neonatal Cephalic	E	E	E		E	E	E		E	E:
Adult Cephalic										
Cardiac [2]	E	E	E		E	E	E		E	E:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E:
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E:
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via Appendix E

Prescription Use Only Per 21 CFR 801 Part D

Concurrence of Center for Devices and Radiological Health (CDRH)

LA332 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

LA435 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

LA522 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

LA523 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

LA532 (6250 systems only)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

LA533 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E:
Abdominal	E	E	E		E	E	E		E	E:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E:
Small Organs [1]	E	E	E		E	E	E		E	E:
Neonatal Cephalic	E	E	E		E	E	E		E	E:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E:
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E:
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:
Other (Urological)	E	E	E		E	E	E		E	E:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via Appendix E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

LA923 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SL3116 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Othe
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]	E	E	E		E	E	E		E	E:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E:
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and

Previously cleared via Appendix
E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

PA023 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P:
Small Organs [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	P:
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

PA122 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P:
Small Organs [1]										
Neonatal Cephalic	P	P	P	P	P	P	P		P	P:
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

PA230 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P:
Abdominal	P	P	P	P	P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P:
Small Organs [1]	P	P	P	P	P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	P:
Cardiac [2]	P	P	P	P	P	P	P	P	P (8)	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

PA240 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P	P	P	P	P		P	P:
Abdominal	P	P	P	P	P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	P:
Small Organs [1]	P	P	P	P	P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	P:
Cardiac [2]	P	P	P	P	P	P	P	P	P (8)	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

BC431 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P	P	P (8)	P:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

BC441 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E:
Abdominal	E	E	E		E	E	E		E	E:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E:
Small Organs [1]	E	E	E		E	E	E		E	E:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	E	E	E		E	E	E		E	E:
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E:
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E:
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:
Other (Urological)	E	E	E		E	E	E		E	E:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via Appendix
E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

BL433 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

BE1123 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P:
Transvaginal	P	P	P		P	P	P		P	P:
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D/4D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

EC123 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	E	E	E		E	E	E		E	E: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5
Transvaginal	P	P	P		P	P	P		P	P: 5
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931, k103152 and Appendix E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

EC1123 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P: 5
Abdominal	E	E	E		E	E	E		E	E: 5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P: 5
Transvaginal	P	P	P		P	P	P		P	P: 5
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E: 5
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P: 5

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931, k103152 and Appendix E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

TEE022 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P:
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

TEE132 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P	P:
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

IOE323 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operation									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)	P	P	P		P	P	P		P	P:
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic	P	P	P		P	P	P		P	P:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	P:
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	P:
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

IOT332 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E:
Abdominal	E	E	E		E	E	E		E	E:
Intraoperative (Abdominal)	E	E	E		E	E	E		E	E:
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E:
Small Organs [1]	E	E	E		E	E	E		E	E:
Neonatal Cephalic	E	E	E		E	E	E		E	E:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E:
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E:
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:
Other (Urological)	E	E	E		E	E	E		E	E:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via Appendix
E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

IOT342 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	E	E	E		E	E	E		E	E:
Abdominal	E	E	E		E	E	E		E	E:
Intraoperative (Abdominal)	E	E	E		E	E	E		E	E:
Intraoperative Neurological										
Pediatric	E	E	E		E	E	E		E	E:
Small Organs [1]	E	E	E		E	E	E		E	E:
Neonatal Cephalic	E	E	E		E	E	E		E	E:
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	E	E	E		E	E	E		E	E:
Laparoscopic										
Musculo-skeletal Conventional [3]	E	E	E		E	E	E		E	E:
Musculo-skeletal Superficial [3]	E	E	E		E	E	E		E	E:
Other (Urological)	E	E	E		E	E	E		E	E:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via Appendix E

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

LP323 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal	P	P	P		P	P	P		P	P:
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	P:
Small Organs [1]	P	P	P		P	P	P		P	P:
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	P:
Laparoscopic	P	P	P		P	P	P		P	P:
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D

[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

TRT33 (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal	P	P	P		P	P	P		P	P:
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	P:
Transvaginal	P	P	P		P	P	P		P	P:
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	P:

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

2CW (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

5CW (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

HFCW (6200 and 6250 systems)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations									
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles
[2] Cardiac is Adult and Pediatric
[3] Musculo Skeletal - Nerve Block
[4] Combined modes are: B+M+PW+CFM+PD

[5] Compound Imaging (Mview)

[6] 3D
[7] CMM

[8] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

Previously cleared via k100931
and k103152

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)